

Remarks

Claim Rejections Under 35 U.S.C. § 102 (Anticipation)

The examiner has rejected claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Lin et al. (U.S. Patent No. 6,071,745). According to the examiner, Lin et al. teaches a kit comprising one or more materials for amplifying a target nucleic acid comprising, among other things, buffers, wherein the buffers comprise a source of phosphate ions and a source of magnesium ions. In support of this teaching, the examiner points to column 7, lines 44-49 of Lin et al.

Applicants respectfully request reconsideration of the examiner's grounds for these claims rejections. The Lin et al. reference at column 7, lines 44-49 teaches the following with respect to buffers: "Another suitable source of isotonic lyophilization solution is TBS. One formulation of TBS contains: 137 mM NaCl, 5 mM KCl, 0.5 mM MgCl₂, 25 mM TRIS base, 0.7 mM Na₂HPO₄, and 0.9 mM CaCl₂. Such solutions are commercially available and are sold in powder form or as premixed sterile solutions." This disclosure does not teach MgHPO₄, as suggested by the examiner. Furthermore, this disclosure does not teach that the source of magnesium ions and the source of phosphate ions form a precipitate at temperatures below 34 °C, as required by claim 1. In fact, the Lin et al. references teaches away from the invention described by claims 1-3. The disclosure relied upon by the examiner teaches that the solution is used for lyophilization purposes, rather than for use as a precipitate. The recital in Lin et al. of the fact that premixed sterile solutions of TBS are commercially available provides further support for this point: such sterile solutions do not contain a precipitate of magnesium and phosphate ions.

Thus, Lin et al. does not teach one limitation of claim 1 that is drawn to "wherein combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the Kit forms a precipitate at a temperature below 34°C." Because claims 2 and 3 depend from claim 1 and contain all the limitations of claim 1, the Lin et al. reference does not anticipate these claims. Applicants respectfully request withdrawal of the rejection of claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Lin et al.

Claim Rejections Under 35 U.S.C. § 103 (Obviousness)

The examiner has rejected claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over Bloch et al. (U.S. Patent No. 5,411,876) in view of Stanley (U.S. Patent No. 6,207,385).

According to the examiner, Bloch et al. teaches generally a kit for amplifying a nucleic acid target, but fails to teach the limitation of claim 1 drawn to “a container comprising a source of phosphate ions and a container comprising a source of magnesium ions, wherein combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the Kit forms a precipitate at a temperature below 34°C.” The examiner asserted that Stanley teaches use of phosphate ions in promoting precipitation (salting out), relying upon column 7, lines 25-43. The examiner thereafter makes the leap in logic to suggest that one of ordinary skill in the art would modify the kit comprising a source of inorganic ions and a source of magnesium ions as disclosed by Bloch et al. in a manner as taught by Stanley with the inclusion of phosphate ions for the purpose of increasing the salting-out process.

Applicants respectfully request reconsideration of the examiner’s grounds for these claims rejections. Stanley discloses the following with regard to inorganic ions and their use in salting out procedures:

Preferably, the aqueous solution in which the molecular species reacts with the optionally purified water-soluble intermediate reagent contains a lyotropic salt, i.e. a salt which has the property, e.g. of promoting the precipitation ("salting-out") of certain types of high molecular weight species, in particular proteins, from aqueous solution. The effectiveness of the incorporation of such a lyotropic salt in enhancing the attachment of molecular species such as oligonucleotides to the reactive vinyl groups present in the water-soluble intermediate reagent is contemplated to derive from the "salting-out" effect mentioned above.

Suitable lyotropic salts may be selected among sulfates, phosphates, citrates and tartrates of lithium, sodium, potassium and ammonium, and the lyotropic salt will normally be present in a concentration corresponding to an ionic strength of at least 0.01, for example a concentration corresponding to an ionic strength of at least 0.3. A suitable concentration will often be a concentration corresponding to an ionic strength in the range of 0.5-5.
(col. 7, lines 26-43)

Importantly, Stanley does not teach that suitable lyotropic salts, i.e., a salt which has the property of promoting precipitation (“salting out”), may be selected among sulfates, phosphates, citrates and tartrates of a divalent cation, such as magnesium. In fact, Stanley teaches away from the use of magnesium by reciting only monovalently-charged cations (lithium, sodium, potassium and ammonium) as suitable counterions with phosphate-based lyotropic salts. See Stanley, col. 7, lines 36-38. Furthermore, Stanley does not teach that lyotropic salts will selectively precipitate at temperatures below 34 °C, as required by claim 1.

In view of the teaching of Stanley, one of ordinary skill in the art would not be motivated to combine the teachings of Bloch et al. with those of Stanley to arrive at the limitation of claim 1 drawn to “combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the Kit forms a precipitate at a temperature below 34°C.” In fact, the examiner’s extended, leapful, explanation of how these two references may be combined further amplifies the fact that no motivation exists for their combination to arrive at the invention as instantly claimed. Furthermore, the examiner has not explained how one of ordinary skill in the art would arrive at the appropriate temperature for precipitation being below 34 °C, as required by the claims based simply upon the teaching of Bloch et al. and Stanley. The examiner has engaged in classic hind sight to arrive at the combination of elements present in these two references that are in fact only found in Applicants’ specification and claims. Therefore, the Bloch et al. reference and the Stanley reference, either alone or in combination, do not teach or suggest the invention of claim 1.

Because claims 2 and 3 depend from claim 1 and contain all the limitations of claim 1, the Bloch et al. reference and the Stanley reference, either alone or in combination, do not teach or suggest all the limitations of these claims. Applicants respectfully request withdrawal of the rejection of claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over Bloch et al. (U.S. Patent No. 5,411,876) in view of Stanley (U.S. Patent No. 6,207,385).

The examiner has rejected claims 4-7 under 35 U.S.C. § 103(a) as being unpatentable over Bloch et al. (U.S. Patent No. 5,411,876) in view of Stanley (U.S. Patent No. 6,207,385), as applied to claims 1-3 above, and further in view of Barnes et al. (U.S. Patent No. 6,214,557). The examiner cites Barnes et al. for the teaching of specific polymerases and according to the examiner, the combined teachings of Bloch et al., Stanley, and Barnes et al. render obvious claims 4-7.

Applicants respectfully request reconsideration of the examiner’s grounds for these claims rejections. For the reasons stated previously, Applicants argue that the examiner has not made a prima facie showing that Bloch et al. in view of Stanley teaches a kit for amplifying a target nucleic acid, particularly with regard to the limitation of claim 1 drawn to “combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the Kit forms a precipitate at a temperature below 34°C.”


Claims 4-7 ultimately depend from claim 1 and contains all the limitations of claim 1. The examiner has failed to show how the combination of these three references teaches or

suggests the limitation at issue missing from Stanley ("combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the Kit forms a precipitate at a temperature below 34°C."), let alone the motivation to combine the references to arrive at the invention of claims 4-7. Applicants respectfully request withdrawal of the rejection of claims 4-7 under 35 U.S.C. § 103(a) as being unpatentable over Bloch et al. (U.S. Patent No. 5,411,876) in view of Stanley (U.S. Patent No. 6,207,385), as applied to claims 1-3 above, and further in view of Barnes et al. (U.S. Patent No. 6,214,557).

Applicants maintain that the claims of the present application are in condition for allowance. Early notification of such allowance is earnestly solicited.

Respectfully submitted,

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